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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,622	06/19/2001	Coenraad Jan Spaans	POLYGANICS-1	8926

7265 7590 10/16/2002
MICHAELSON AND WALLACE
PARKWAY 109 OFFICE CENTER
328 NEWMAN SPRINGS RD
P O BOX 8489
RED BANK, NJ 07701

EXAMINER

GORR, RACHEL F

ART UNIT	PAPER NUMBER
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1711

DATE MAILED: 10/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/701,622		SPAANS ET AL	
	Examiner		Art Unit	
	Rachel Gorr		1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 34-60 is/are pending in the application.
- 4a) Of the above claim(s) 56 and 58-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 34-39, 41-45, 47-50, 54 and 55 is/are rejected.
- 7) ☐ Claim(s) 42, 46, 51-53 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1 ☒ Certified copies of the priority documents have been received.
2 ☐ Certified copies of the priority documents have been received in Application No. _____.
3 ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

1. Newly submitted claims 56 and 58-60 are directed to an invention that lacks unity with the invention originally claimed for the following reasons: Claims 56 and 58 are directed to isocyanate terminated prepolymers. These prepolymers don't have the share the same technical feature as the hydroxy terminated prepolymer of claim 44. The process claims of 59 and 60 don't have the same technical features as the process claims of 40 and 46, which involve the use of solvents.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 56 and 58-60 are withdrawn from consideration as being directed to a nonelected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. Claims 43 and 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 43, the phrase, "based on number", isn't understood.

Claim 57 is confusing because the preceding claim doesn't have any antecedent basis for "YXY".

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claim 44 is rejected under 35 U.S.C. 102(b) as being anticipated by Ambrose.

Ambrose discloses glycols made from butane diisocyanate (col. 6, line 41) and diethylene glycol or hexane diol (col. 6, lines 25-26).

5. Claims 34, 35, 38, 45, 49, 50 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Quay.

See Paper No. 7, paragraph 12.

6. Applicant's arguments filed 9-10-02 have been fully considered but they are not persuasive. The applicants argue that Quay isn't biodegradable. The Quay polyurethane is based on some of the same polyesters disclosed by the applicants, and the polyester is hydrolyzed by moisture in the body. The applicants argue that cyclohexane diisocyanate used by Quay is toxic. All isocyanate compounds are toxic. The isocyanate group reacts with water in the tissues of the nose and lungs. Once they are incorporated into polyurethanes, they are no longer toxic. Polyurethanes have wide use in biomedical applications.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 34-39, 41, 45, 47-49, 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Groot (New Biomedical...) in view of Cohn, de Groot (Use of Porous...) and Gogolewski.

9. De Groot (New..) discloses polyurethanes made from caprolactone polyester polyols and butane diisocyanate (see summary). He shows polyurethanes having a homogeneous block structure. The polyester is reacted with an excess of diisocyanate (top page 212) and the excess unreacted diisocyanate is removed to make the polyester terminated with two diisocyanates. He uses these polyurethanes for medical applications. He differs from the claims by chain extending the prepolymer with a diamine rather than with a diol, by not showing porous polyurethanes, by not showing the specific application of meniscal reconstruction and by not disclosing polyesters of lactic acid.

10. Cohn teaches that polyurethanes for biodegradable medical applications can be chain extended with diamines or diols (col. 4, lines 1-18).

11. De Groot (Use ..)discloses using porous polyurethanes for meniscal reconstruction.

12. Gogolewski discloses biodegradable polyurethanes made from copolymers of lactic acid and ethylene glycol (col. 2, lines 7-9).

13. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute a diol for the diamine of de Groot (New..) because Cohn teaches that these polyurethanes are more easily dissolved or melted for shaping medical articles (top col. 4). It would have been obvious to make the polyurethane porous and use it for meniscal reconstruction because de Groot (Use...) discloses this as an application for medical polyurethanes. It would have been obvious to use polyesters of lactic acid because Gogolewski shows this for biodegradable

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polyurethanes. Lactic acid is known to be biocompatible because it can be found in foods.

14. Applicant's arguments filed 9-10-02 have been fully considered but they are not persuasive. The applicants argue that Cohn doesn't disclose the same reasons for using diol chain extenders as the applicants. The references aren't required to show the same motivation. They argue that de Groot is biostable and Cohn is biodegradable. Both references are directed to biodegradable polyurethanes.

15. Claims 40, 42, 46, 51-53 are objected to for depending on rejected claims.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel Gorr whose telephone number is (703) 308-3608. The examiner can normally be reached on Mon., Tues., Thurs., Fri., from 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jim Seidleck can be reached on (703) 308-2462. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


RACHEL GORR
PRIMARY EXAMINER